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Lap-Band maker needs to step up

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Like most big companies, Irvine pharmaceutical giant Allergan Inc. likes to project the image of an upstanding corporate citizen. Indeed, it devotes several pages of its website to its purported good works.

Yet it's still proper to ask: When will Allergan move from merely projecting the image -- and start accepting the real responsibilities -- of corporate citizenship?

The question arises from last week's action by the Food and Drug Administration against the high-profile marketers of one of Allergan's products. The product is the Lap-Band, a silicone ring implanted around the stomach to suppress appetite in exceptionally obese patients, and the marketers are 1-800-GET-THIN and what lawsuits, coroners reports and other public records have identified as its affiliated surgery centers.

There can hardly be a resident of Southern California unfamiliar with 1-800-GET-THIN, which has blanketed the community with freeway billboards, bus placards, and radio and TV ads, many of which make extravagant claims for the safety and efficacy of the Lap-Band as though it's an instant panacea. They've featured testimonials from patients, some of whom claimed to have lost more than 100 pounds, and state that weight losses "typically" run 1-2 pounds per week, that the procedure takes one hour and that it's virtually risk-free.

I've observed in the past that 1-800-GET-THIN and its affiliated clinics pose a problem for Allergan, which supplies the surgery centers with the Lap-Band. For one thing, there are the questions about quality of care, given that four Southland patients have died after surgeries performed at clinics that have been affiliated with the ad campaign, according to public records.

A coroner's ruling is still pending on the death of a fifth patient, who expired after being rushed to a hospital in September from the surgery center where she had just undergone the procedure.

Then there's the issue of how the Lap-Band is advertised by 1-800-GET-THIN, a point sharpened by the FDA's action last week.

The FDA says the firm's ads violate federal law by downplaying the risks, side effects and complications of Lap-Band surgery, up to and including the risk of death from the operation. As a consequence, FDA officials say, the procedure may be getting pitched at patients who aren't suitable or for whom the risks of surgery are especially high. This includes the morbidly obese, which is why professional standards in weight-loss surgery require that candidates for the procedure be very carefully screened -- screening that isn't necessarily consistent with a freeway billboard campaign.

Oh, sure, in recent months GET-THIN's billboards have incorporated a pro forma disclaimer mentioning that there may be some downsides to Lap-Band operations. But as the FDA reports, this is typically printed in such minuscule type that an ordinary motorist scanning a billboard from the road would be hard-pressed to know it was a disclaimer, much less what it said.

The agency gave the promoters two weeks to say how they'll change the ads, or they'll be subject to further legal action including monetary penalties and seizure of their Lap-Band inventory.

As for Allergan, one might surmise that as the manufacturer of the nation's bestselling gastric band, the company would have a strong interest in seeing that its product is not marketed misleadingly or illegally. Allergan's chairman, David Pyott, has told The Times that the company is unhappy with the way GET-THIN

markets its weight-loss device; other executives say Allergan doesn't believe it can mandate any changes.

Earlier this year, Allergan did issue a set of "guidelines" for outside advertising of the Lap-Band. Among other things, it says the ads should "comply with all applicable laws," be "truthful and not misleading" and provide "important risk information, including potential adverse events associated with the procedure."

Judging from the FDA's action, one might conclude that the 1-800-GET-THIN ads flagrantly flout all those guidelines. But when I asked an Allergan spokeswoman last week how the company intended to enforce them, she replied that it had no such intention.

"We don't have any authority over physician advertising," the spokeswoman, Caroline Van Hove, told me. "That's why these are 'guidelines.'"

Allergan has consistently tried to distance itself from 1-800-GET-THIN and individual medical practices, saying that they're independent entities.

But Allergan is deeply entwined in a commercial relationship with 1-800-GET-THIN and the clinics to which the marketing service refers callers. GET-THIN has identified itself in legal papers as a firm that "provides marketing for the Lap-Band® procedure" (that symbol identifies "Lap-Band" as an Allergan trademark), and the GET-THIN ads and websites bristle with references to the trademark. Its affiliated clinics appear to use the Allergan device exclusively.

The FDA says it "does not have any reason to believe that Allergan has violated its legal responsibilities" in its own Lap-Band marketing, in the words of Steven D. Silverman, the agency's compliance director for medical devices, who signed the warning letters to GET-THIN and its affiliated clinics.

Yet surely a company that manufactures a medical device has a higher duty than one turning out, say, machine tools. That's the FDA's feeling.

"There's a difference between the legal requirements and good corporate citizenship," Silverman told me after the FDA announced its decision last week. "If they're aware that their devices are being improperly marketed, it's a question of good public citizenship whether they need to go above and beyond the legal requirements."

That question, he added, covers whether they should be providing the device to practitioners who may be misleading the public about its balance of risks and benefits.

You can feel a certain sympathy for Allergan. There may indeed be some legal question about whether the company could, say, cut off the Lap-Band supply to GET-THIN's affiliated clinics. Company executives have told The Times that the answer is no, "except for cause." Even allegations of surgery-related deaths don't qualify as cause, they said, at least until the allegations are finally adjudicated in court.

Still, it's hard to believe that if it really wanted to shed 1-800-GET-THIN -- or indeed anyone -- as a customer, Allergan couldn't find a legally sound rationale for doing so.

But Allergan also faces a troubling conflict of interest. Anti-obesity products, mostly the Lap-Band, are its worst performing category, with sales shrinking by more than 14% in the first nine months of this year compared with a year earlier. Bariatric (that is, weight-loss) surgeries declined by 9% in the United States during the first eight months of 2011 compared with a year earlier, Pyott told investors recently -- and gastric bands accounted for a shrinking percentage of the procedures that were done.

The best thing Pyott had to say about the shrinking gastric-band market was that Allergan's share of it was increasing, to 82% in August from 70% a year earlier. It would be interesting to know how much of that increase was due to the aggressive advertising by the 1-800-GET-THIN folks, and whether that might explain why Allergan seems so unwilling to help put the kibosh on their marketing campaign.

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PHOTO: A BILLBOARD AD along the 5 Freeway is part of the 1-800-GET THIN campaign for the Lap-Band.; PHOTOGRAPHER: Mariah Tauger Los Angeles Times

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